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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,498	04/15/2004	Todd R. Henderson	024047.370B-US02	6565

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,498	HENDERSON ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-62* is/are pending in the application.

4a) Of the above claim(s) *31,32,42,52 and 62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-30,33-41,43-51 and 53-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/15/2004;7/19/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 31, 32, 42, 52 and 62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 10, 2007.

2. Applicant's election with traverse of invention group I in the reply filed on August 10, 2007 is acknowledged. Applicant's election with traverse of glucosamine or its salts as elected aminosugar, and chondroitins as elected glycosaminoglycan in the reply filed on August 10, 2007 is acknowledged. The traversal is on the ground(s) that groups I and II are related and search of all the invention would not be an undue burden. This is not found persuasive because the inventions are independent and distinct for reasons set forth in prior office action and search of the method claims is not required for the composition claims. Further, note the search is not limited to patent literature.

3. Applicants also argue that N-acetylglucosamine should be examined with glucosamine because of the similarity of their structures and known properties. These arguments are persuasive and N-acetylglucosamine would be examined with glucosamine.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting Rejections

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 6-30, 33-41, 43-51, 53-61 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1-4 of U.S. Patent No. 6,797,289 in view of Herderson (US 5,587,363, IDS).

6. '289 claims a composition for the treatment, repair of damage to connective tissue comprising a synergistic combination of glucosamine and avocado/soybean unsaponifiables. The claimed subject matter in '289 would read on claims 7, 29, 33, 43, 53 and their dependent claims. The claims do not expressly claims the employment of glycosaminoglycan, such as chondroitin, as recited in claim 6. However, Herderson teaches a composition comprising glucosamine and chondroitin sulfate, and method of using the same for treatment or reparation of connective tissue, in patient such as osteoarthritis or arthritis. The dosage of glucosamine is about 250 mg to 3000 mg, and the dosage of chondroitin sulfate is about 250 to 1000 mg. See, particularly, the abstract, col. 1, lines 23-31, col. 10, lines 54-64 and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to further incorporate chondroitin compounds into the composition as claimed in '289

A person of ordinary skill in the art would have been motivated to further incorporate chondroitin compounds into the composition as claimed in '289 because chondroitin is known to be useful for treatment, or protection of connective tissue. It is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art. See In re Kerkhoven, 205 USPQ 1069.

Claims 6-30, 33-41, 43-51, 53-61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-43, 46-54 of copending Application No. 11/634,383. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims herein are generic to claims recited in '383. Further, the employment of an ant-inflammatory agent, such as COX-2 inhibitor, for treatment of arthritis would have been obvious as inflammation is a well recognized symptom associated connective tissue conditions, such arthritis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections 35 U.S.C. 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 12, 21-28, 40, 41, 50, 51, 58, 60 and 61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitations of "mannosamine" (claim 12) and "pentosan polysulfate" (claim 58) lack support from the application as originally filed and constitute new mater. Further, the recited amounts for aminosugar and glycosamineglycan in the claims lack support from the application as originally filed. It is noted that the amounts herein are disclosed in the specification particularly for glucosamine and chondroitin, not generally for aminosugar and glycosamineglycan. See pages 31-33 of the specification.

9. Claims 6-30, 33-41, 43-51, 53-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment or repair of connective tissue damage and/or inflammation, does not reasonably provide enablement for prevention of tissue damage and/or inflammation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Attention is directed to In re Wands, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

The claim recites the prevention of connective tissue damage and/or inflammation for the claimed composition. The prior art and the application show the composition or the active ingredients thereof are useful for treatment of connective tissue disorders (such as arthritis), or suppressing the symptoms of those disorders. However, applicants fail to provide information allowing skilled artisan to ascertain the usefulness of the composition for prevention the disorder without undue experimentation. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed of physiological activity. For example, arthritis may be caused by several distinct etiologies, such as autoimmune disorder, aging, hormone deficiency, etc. The application lack sufficient guidance, direction or working examples to show that the claimed composition is capable for preventing the diseases caused by various distinct etiologies. Therefore, one of ordinary skill in the art would have to perform an undue experimentation to assure if the claimed composition is indeed to be useful for prevention the disorders.

Claim Rejections 35 U.S.C. 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 6-30, 33-41, 43-51, 53-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herderson (US 5,587,363, IDS) in view of Thiers (IDS, CV4), Lamaud et al. (IDS, CW2)) and Blotman et al (IDS, CR), and applicants' admission at pages 20.

12. Herderson teaches a composition comprising glucosamine and chondroitin sulfate, and method of using the same for treatment or reparation of connective tissue, in patient such as osteoarthritis or arthritis. The dosage of glucosamine is about 250 mg to 3000 mg, and the dosage of chondroitin sulfate is about 250 to 1000 mg. See, particularly, the abstract, col. 1, lines 23-31, col. 10, lines 54-64 and the claims.

13. Herderson does not teach expressly the employment of an avocado/soybean unsaponifiables.

14. However, as applicants admitted (page 20 of the specification), avocado/soybeen unsaponifiables has been known as useful for treatment of arthritis, citing Thiers, Lamaud et al. and Blotman et al. There three references teach that avocado/soybean unsaponifiable is known to be useful for treatment of osteoarthritis. See, the abstracts of the three references.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to further incorporate avocado/soybean unsaponifiables in Herderson's composition.

It is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of two agents known to be useful for treating osteoarthritis set forth prima facie obvious subject matter. See In re Kerkhoven, 205

USPQ 1069. As to the particular amount of each and every active ingredients herein recited, The optimization of a result effective parameter, e.g., effective amounts of active therapeutical agents, is considered within the skill of the artisan, absent evidence to the contrary. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shengjun Wang
Primary Examiner
Art Unit 1617

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